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Election

Patent
Attorney's Docket No. 001560-336

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Patent Application of | ) | |
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| Norio INOMATA et al | ) | Group Art Unit: 1654 |
| | ) | |
| Application No.: 09/171,928 | ) | Examiner: BORIN |
| | ) | |
| Filed: October 5, 1998 | ) | |
| | ) | |
| For: PHARMACEUTICAL COMPOSITION FOR TREATMENT OF HEART DISEASE BASED ON CARDIAC HYPERTROPHY | ) | FEB 15 2000<br>TECH CENTER 1600/2900 |

**RESPONSE TO RESTRICTION REQUIREMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In complete response to the Official Action dated December 9, 1999, requiring restriction pursuant to 35 U.S.C. §§ 121 and 372, Applicants offer the following reply.

Applicants provisionally elect with traverse to prosecute the invention of Group II, claims 6-14, drawn to methods of using the pharmaceutical composition. It is noted that Group II should begin with claim 6 rather than claim 7, as identified in the Official Action.

Applicants respectfully submit that unity of invention exists at the very least with respect to Groups I and II identified by the Examiner. In accordance with 37 C.F.R. § 1.475(b)(2), unity of invention exists in a national stage application if the claims are drawn to the combination of a "product and a process of use of said product." Since the Group I claims recite a pharmaceutical composition and the Group II claims recite a method of using same, unity of invention exists under §1.475(b)(2).

In accordance with §1.475(a), unity of invention exits if the inventions are "linked as to form a single general inventive concept." The requirement of unity of invention is said to be met "when there is a technical relationship among those inventions involving one or more of the same technical features" which is said to define the contribution of the claimed invention over the prior art. In the instant application, the technical feature which links the composition and method of use claims is "a substance that acts on the natriuretic peptide receptor, guanylyl cyclase A, and is able to accelerate production of cyclic guanosine monophosphate is a natriuretic peptide."

Both the composition and method claims recite the use of such a substance. Group I claims recite a "pharmaceutical composition for treatment of heart disease based on cardiac hypertrophy comprising as its active ingredient a substance that acts on the natriuretic peptide receptor, guanilyl cyclase A, and is able to accelerate production of cyclic guanosine monophosphate." Group II claims a "method for treatment of heart disease based on cardiac hypertrophy comprising administrating a substance that acts on the natriuretic peptide receptor, guanylyl cyclase A, and is able to accelerate production of cyclic guanosine monophosphate, to a subject in a need of such treatment in an amount effective for treating said heart disease." Since the Group I and II claims recite a "pharmaceutical composition for treatment of heart disease based on cardiac hypertrophy" and a "method for treatment of heart disease based on cardiac hypertrophy," respectively, which both recite the same substance, the claims are linked "to form a single general inventive concept." The "inventive concept" is thus compositions for treatment of, and treatment of, heart diseases which are based on cardiac hypertrophy by using a substance

which acts on a NP-receptor (GC-A) so as to produce cGMP. This "inventive concept" defines the contribution of the claimed invention over the prior art. Unity of invention thus exists.

Moreover, according to the MPEP § 803, a restriction between patentably distinct inventions is proper only where there is a serious burden on the Examiner to examine all the claims in a single application. This is true even when appropriate reasons exist for a restriction requirement. In the present application, it is believed that because there is a close relationship between the subject matter of the Group I and II claims, there would be no serious burden on the Examiner to both sets of claims at this time. Claims 1-5 and 15-19 relate to pharmaceutical compositions comprising a substance that acts on the natriuretic peptide receptor, guanylyl cyclase A, and is able to accelerate production of cyclic guanosine monophosphate is a natriuretic peptide." Claims 6-14 relate to a method of use of the pharmaceutical compositions. In light of the close relationship between the subject matter of these two sets of claims, it is respectfully believed that a search directed to the claims of Group II, would include a search directed to the subject matter of the claims of Group I. Thus, there would be no serious burden on the Examiner to examine all of claims 1-19 at this time.

In light of the above, withdrawal of the requirement for restriction between Groups I and II is respectfully requested. Such action is believed to be in order.

Further and favorable consideration of all the claims of record on the merits is respectfully requested.

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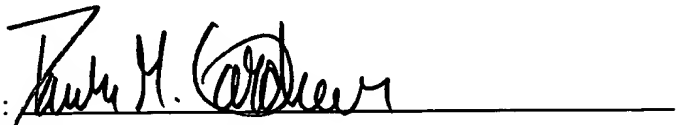
In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 

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